Atty. Dkt. No. 056324-0129



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: R. Tyler WHITE et al.

Title: PROTEASE INHIBITOR PEPTIDES

Appl. No.: 10/076,604

Filing Date: 02/19/2002

Examiner: E. Slobodyansky

Art Unit: 1652

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants submit herewith on Form PTO/SB/08 a listing of the documents cited by or submitted to the U.S. PTO in parent application Serial No. 09/201,715, filed 12/01/1998. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

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TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

FEE

A fee in connection with submission of an information disclosure statement under 37 CFR §1.97(c) in the amount of \$180.00 in accordance with 37 CFR §1.17(p) is attached.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date August 23, 2004

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Matthew E. Mulkeeen Registration No. 44,250 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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	INFORMATION DI	SCLO	SURE	Application Number	10/076,604		
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	CY			First Named Inventor	R. Tyler White	<u> </u>	
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U.S. PATENT DOCUMENTS								
Examiner	Cite No.1	U.S. Patent [Document		Date of Publication of	Pages, Columns, Lines, Where Relevant		
Examiner Initials*		Number	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear		
	A1	5,436,153		SPRECHER ET AL.	07/25/1995			
	A2	5,223,409		LADNER ET AL.	06/29/1993			
	A3	5,403,484		LADNER ET AL.	04/04/1995			
	A4	5,187,153		CORDELL ET AL.	02/16/1993			
	A5	5,223,482		SCHILLING JR. ET AL.	06/29/1993			
-	A6	5,373,090		NORRIS ET AL.	12/13/1994			
	A7	5,441,931		SPRECHER ET AL.	08/1995			
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	A8	ΕP	90 10 6529.	2		10/24/1990		
	A9	wo	92/15605			09/17/1992		
	A10	wo	93/09233			05/13/1993		
	A11	wo	96/39519			12/12/1996		
	A12	wo	93/14120			07/1993		
	A13	WO	93/14119			08/1993		
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*Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. *Applicant is to place a check mark here if English language Translation is attached.

MODIFIED PTO/SB/08 (08-00)

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ĺ	INFORMATIO	N DISCLOS	SURE	Application Number	10/076,604		
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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A16	DENNIS, M. et al., "Kunitz Domain Inhibitors of Tissue Factor-Factor VIIa", J. of Biol. Chem., Vol. 269, No. 35, Sept. 2, pp. 22129-136, 1994.	
	A17	COLMAN, R., "Factor XII Activation and Inhibition In Inflammation", <i>Proteases, Protease Inhibitors and Protease-Derived Peptides</i> , pp. 125-43, 1993.	
	A18	SCOTT, C. <i>et al.</i> , "Kinetics of Inhibition of Human Plasma Kallikrein by a Site-Specific Modified Inhibitor Arg ¹⁵ -Aprotin: Evaluation Using a Microplate System & Comparison with Other Proteases", <i>Blood</i> , Vol. 69, No. 5 (May), 1987: pp. 1431-36.	
·	A19	PATSON, P. <i>et al.</i> , "Reactivity of α ₁ -Antitrypsin Mutants against Proteolytic Enzymes of the Kallikrein-Kinin, Complement, and Fibrinolytic Systems", <i>J. of Biol. Chem.</i> , Vol. 265, No. 18, pp. 10786-91, June 25, 1990.	
	A20	WEN, L. et al., "Chemical Synthesis, Molecular Cloning, Overexpression, and Site-Directed Mutagenesis of the Gene Coding for Pumpkin (Curcubita maxima) Trypsin Inhibitor CMTI-V", Protein Expression and Purification 4, pp. 215-22 (1993).	
	A21	PEDERSEN, L. et al., "The Corn Inhibitor of Blood Coagulation Factor XIIa, Crystallization and Preliminary Crystallographic Analysis", <i>J. Mol. Biol.</i> (1994) 236, pp. 385-87.	
	A22	PONTE, P. et al., "A New A4 Amyloid mRNA contains a domain homologous to serine proteinase inhibitors", <i>Nature</i> , Vol. 331, pp. 525-527, February 11, 1988.	
	A23	TANZI, R. et al., "Protease Inhibitor Domain Encoded by an Amyloid Protein Precursor mRNA associated with Alzheimer's Disease", <i>Nature</i> , Vol. 331, pp. 528-530, Feb. 11, 1988.	
	A24	JOHNSTONE, E. et al., "Alzheimer's Disease Amyloid Peptide is Encoded by Two Exons and Shows Similarity to Soybean Trypsin Inhibitor", <i>Biochem. & Biophys. Res. Comm.</i> , Vol. 163, No. 3, pp. 1248-1255, Sept. 29, 1989.	
	A25	WENZEL, H. et al., "Semisynthetic Conversion of the Bovine Trypsin Inhibitor (Kunitz) into an Efficient Leukocyte-Elastase Inhibitor by Specific Valine for Lysine Substitution in the Reactive Site", Chem. of Peptides and Proteins, Vol. 3, pp. 105-117, (1986).	
	A26	NORRIS, K. <i>et al.</i> , "Aprotinin and Aprotinin Analogues Expressed in Yeast", Walter de Gruyter & Co., pp. 37-42, May 1990.	
	A27	PERONA, J.J. et al., "Cyrstal Structures of Rat Anionic Trypsin Complexed with Protein Inhibitors APPI and BPTI", J. Mol. Biol. (1993) 230:919-933.	
	A28	SINHA S. et al., "Conversion of the Alzheimer's β-Amyloid Precursor Protein (APP) Kunitz domain into a Potent Human Neutrophil Elastase Inhibitor", <i>J. of Biol. Chem.</i> , Vol. 266, No. 31, (1991), pp. 21011-13.	

			
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Ι.	AU6 2 3 2004 STATEMENT BY APPLICANT Day Submitted: August 23, 2004				Filing Date	02/19/2002	
					First Named Inventor	R. Tyler White	
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·T		as many sheets a	as ne	cessary)	Examiner Name	E. Slobodyansky	
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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A29	OLTSERDORF, T. et al., "The secreted form of the Alzheimer's amyloid precursor protein with the Kunitz domain is protease nexin-II", Nature, Vol. 341, pp. 144-147, Sept. 14, 1989.	
	A30	HYNES, T.R. et al., "X-ray Crystal Structure of the Protease Inhibitor Domain of Alzheimer's Amyloid β-Protein Precursor", <i>Biochemistry</i> , Vol. 29, No. 43, (1990), pp. 10018-22.	
	A31	DENNIS, M.S. et al., "Kunitz Domain Inhibitors of Tissue Factor-Factor VIIa", <i>J. Biological Chemistry</i> , Vol. 269, No. 35, (1994), pp. 22129-36.	
	A32	DENNIS, M.S. et al., "Kunitz Domain Inhibitors of Tissue Factor-Factor VIIa", <i>J. Biological Chemistry</i> , Vol. 269, No. 35, (1994), pp. 22137-44.	
	A33	KIDO, H. et al., "Protease-Specificity of Kunitz Inhibitor Domain of Alzheimer's Disease Amyloid Protein Precursor", <i>Biochemical and Biophysical Research Communications</i> , Vol. 167, No. 2, (1990), pp. 716-721.	
	A34	DENNIS, M.S., "Potent and Selective Kunitz Domain Inhibitors of Plasma Kallikrein Designed by Phage Display", <i>Journal of Biological Chemistry</i> , Vol. 270, No. 43, (1995), pp. 25411-17.	

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